OCT 2 4 2001

## ATTACHMENT 11

## 510(k) SUMMARY K001974

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|---|---|
| Submitting Company: | Mayer Laboratories, Inc.<br>646 Kennedy St., Bldg. C<br>Oakland, CA 94606 |
| Telephone: | 510-437-8989 |
| Fax: | 510-536-9912 |
| Contact Person: | David P. Mayer<br>President |
| Date Prepared: | June 12, 2000 |
| Common Product Name: | Condom |
| Proprietary Name: | eZ-on™ Condom |
| Classification Name: | Condom (per 21 CFR 884.5300) |

Product Description: The eZ-on™ condom is a condom made from a polyurethane material (non-latex material) that has similar physical properties and general form to latex condoms. The eZ-on™ condom is a sheath that covers the penis and acts as a physical barrier to passage of semen. The eZ-on™ condom completely covers the penis with a non-constricting membrane of polyurethane film. The sheath is retained on the penis by a polyurethane flange, having an aperture that is smaller than the circumference of the penis. The aperture of the flange retention mechanism has a nominal diameter of 28 mm. The nominal length of the condom is 171 mm, and the nominal width is 70 mm. The sheath of the condom has a minimum nominal (single wall) thickness of 0.035 mm. The sheath is "center-rolled" to facilitate unrolling and application in either direction. The condom is lubricated with medical grade silicone oil.

Intended Use: To prevent pregnancy and to prevent the spread of sexually transmitted diseases. When used correctly and consistently, condoms are an effective means of preventing pregnancy, although no contraceptive can guarantee 100% protection. If used properly, condoms will help reduce the risk of transmission of HIV/AIDS, and many other sexually-transmitted diseases. For maximum benefit, it is important to follow the instructions for use that accompany the product.

Substantial Equivalence: The eZ-on™ condom is substantially equivalent to (1) polyurethane condoms from Apex Medical Technologies, Inc., 510(k) Number K902936, marketed as "Durex Avanti", (2) polyurethane condoms from Carter Products, 510(k) Numbers K942697 and K955672, marketed as "Trojan Supra", and (3) non-latex condoms from Tactyl Technologies, Inc. (aka: Sensicon Corporation), 510(k) Numbers K911431, K971590, and K974121, known as "Tactylon".

Technological Characteristics: The eZ-on™ condom has the same technological characteristics as the predicate devices named in the section, "Substantial Equivalence."

Safety and Effectiveness Testing: The eZ-on™ condom and its material have been subjected to extensive laboratory and clinical testing. Toxicity and viral permeability test data show that the material is non-toxic and that it provides a substantial barrier to viral penetration. Clinical test data show that breakage and slippage rates for the eZ-on™ condom are similar to legally marketed non-latex condoms. The contraceptive effectiveness for the eZ-on™ condom is not known; a clinical study is currently underway to determine contraceptive effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2001

Mr. David P. Mayer
President
Mayer Laboratories, Inc.
646 Kennedy Street
Building C
OAKLAND CA 94606

Re: K001974
Trade/Device Name: eZ·on™ Polyurethane Male Condom
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 MOL
Dated: August 8, 2001
Received: August 9, 2001

Dear Mr. Mayer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

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| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K001974

OCT 24 2001

## ATTACHMENT 12

## INDICATIONS FOR USE SUMMARY

510(k) Number: K001974

Company Name: Mayer Laboratories, Inc.

Device Name: Condom; per 21 CFR 884.5300

Indications for Use: Indications for use of the eZ-on™ condom are situations where a non-latex condom is desired to prevent pregnancy and/or to prevent the spread of sexually transmitted diseases.

Concurrence of CDRH, Office of Device Evaluations (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K001974